

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of the Claims:

1. (Currently Amended) A composition for oral administration comprising arsenic trioxide, wherein the said composition is prepared by a method comprising:

(a) adding arsenic trioxide to sterile water to form a first solution/suspension;

(b) adding sodium hydroxide to the said first solution to form a second solution/suspension; and

(c) adding hydrochloric acid to the said second solution to form a third solution.

2. (Original) The composition of claim 1, wherein the arsenic trioxide in step (a) is a powder.

3. (Original) The composition of claim 2, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

4. (Currently Amended) The composition of claim 1, wherein the sodium hydroxide has a molar concentration of the sodium hydroxide is 3M.

5. (Currently Amended) The composition of claim 1, wherein the hydrochloric acid has a molar concentration of the hydrochloric acid is 6M.

6. (Currently Amended) The composition of claim 5, wherein the pH of the third solution [[is]] has a pH of 8.0.

7. (Currently Amended) The composition of claim 1, further comprising the step of adding dilute hydrochloric acid and sterile water to the third solution to form a final solution.

8. (Original) The composition of claim 7, wherein the final solution has a pH of 7.2.

9. (Original) The composition of claim 7, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

10. (Currently Amended) A composition for oral administration comprising arsenic trioxide, wherein the said composition is prepared by a method comprising:

(a) a first step of adding 500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution/suspension;

(b) a second step of adding 3M sodium hydroxide to the said first solution/suspension to form a second solution;

(c) a third step of adding 250 ml of sterile water to the said second solution to form a third solution;

(d) a fourth step of adding 6M hydrochloric acid to the said third solution to form a fourth solution; and

(e) a fifth step of adding dilute hydrochloric acid and sterile water to the said fourth solution to form a final solution.

11. (Original) The composition of claim 10, wherein the arsenic trioxide in step (a) is a powder.

12. (Original) The composition of claim 11, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

13. (Previously Presented) The composition of claim 10, wherein the arsenic trioxide is incompletely dissolved in the first solution.

14. (Original) The composition of claim 10, wherein the arsenic trioxide is completely dissolved prior to adding the hydrochloric acid in step (d).

15. (Currently Amended) The composition of claim 10, wherein the ~~pH~~ of the fourth solution [[is]] has a pH of 8.0.

16. (Original) The composition of claim 10, wherein the final solution has a pH of 7.2.

17. (Original) The composition of claim 10, wherein the final solution has a final volume of 500 ml.

18. (Original) The composition of claim 10, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

19. (Currently Amended) A method for making an arsenic trioxide composition for oral administration comprising:

(a) a first step of adding 500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution/suspension;

(b) a second step of adding 3M sodium hydroxide to the said first solution/suspension to form a second solution;

(c) a third step of adding 250 ml of sterile water to the said second solution to form a third solution;

(d) a fourth step of adding 6M hydrochloric acid to the said third solution to form a fourth solution; and

(e) a fifth step of adding dilute hydrochloric acid and sterile water to the said fourth solution to form a final solution ~~The method of claim 18, wherein the arsenic trioxide has at least 90%, 95%, 96%, 97%, 98% or 99% purity.~~

20. (Original) The method of claim 19, wherein the arsenic trioxide in step (a) is a powder.

21. (Original) The method of claim 20, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

22. (Previously Presented) The method of claim 19, wherein the arsenic trioxide is incompletely dissolved in the first solution.

23. (Original) The method of claim 19, wherein the arsenic trioxide is completely dissolved prior to adding the hydrochloric acid in step (d).

24. (Currently Amended) The method of claim 19, wherein the ~~pH of the~~ fourth solution ~~[[is]]~~ has a pH of 8.0.

25. (Original) The method of claim 19, wherein the final solution has a pH of 7.2.

26. (Original) The method of claim 19, wherein the final solution has a final volume of 500 mL.

27. (Original) The method of claim 19, wherein the final solution has an arsenic trioxide concentration of 1 mg/mL.

28. (Currently Amended) A method of treating hematological malignancies in a subject in need thereof, the said method comprising administering to the said subject a therapeutically effective amount of an arsenic trioxide composition, wherein the said arsenic trioxide composition is prepared by a method comprising:

(a) a first step of adding 500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution/suspension;

(b) a second step of adding 3M sodium hydroxide to the said first solution/suspension to form a second solution;

(c) a third step of adding 250 ml of sterile water to the said second solution to form a third solution;

(d) a fourth step of adding 6M hydrochloric acid to the said third solution to form a fourth solution; and

(e) a fifth step of adding dilute hydrochloric acid and sterile water to the said fourth solution to form a final solution.

29. (Original) The method of claim 28, wherein the arsenic trioxide in step (a) is a powder.

30. (Original) The method of claim 29, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

31. (Previously Presented) The method of claim 28, wherein the arsenic trioxide is incompletely dissolved in the first solution.

32. (Original) The method of claim 28, wherein the arsenic trioxide is completely dissolved prior to adding the hydrochloric acid in step (d).

33. (Currently Amended) The method of claim 28, wherein the pH of the fourth solution [[is]] has a pH of 8.0.

34. (Original) The method of claim 28, wherein the final solution has a pH of 7.2.

35. (Original) The method of claim 28, wherein the final solution has a final volume of 500 ml.

36. (Original) The method of claim 28, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

37. (Currently Amended) The method of claim 28, wherein the administering to the subject is oral arsenic trioxide composition is orally administered to the subject.

38. (Original) The method of claim 37, wherein the arsenic trioxide composition is orally administered to the subject for at least a month.

39. (Previously Presented) The method of claim 28, wherein the therapeutically effective amount is 10 mg per day.

40. (Original) The method of claim 28, wherein the hematological malignancies is selected from the group consisting of acute myeloid leukemia, acute nonlymphocytic leukemia, myeloblastic leukemia, promyelocytic leukemia, myelomonocytic leukemia, monocytic leukemia, erythroleukemia, myelodysplastic syndrome, acute promyelocytic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, hairy cell leukemia, polycythemia vera, Hodgkin's lymphoma, non-Hodgkin's lymphomas, myeloma, giant cell myeloma, indolent myeloma, localized myeloma, multiple myeloma, plasma cell myeloma, sclerosing myeloma, solitary myeloma, smoldering multiple myeloma, nonsecretory myeloma, osteosclerotic myeloma, plasma cell leukemia, solitary plasmacytoma, and extramedullary plasmacytoma.

41. (Original) The method of claim 28, wherein the hematological malignancies is acute myeloid leukemia.

42. (Original) The method of claim 28, wherein the hematological malignancies is acute promyelocytic leukemia.